



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410 and 414

[CMS-6088-N]

RIN 0938-ZB76

Medicare Program; Updates to Face-to-Face Encounter and Written Order Prior to Delivery List

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Update to certain codes.

SUMMARY: This document announces updates to the Healthcare Common Procedure Coding System (HCPCS) codes on the Required Face-to-Face Encounter and Written Order Prior to Delivery List.

DATES: The implementation is effective on [Insert date 90 days after the date of publication in the **Federal Register**].

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SUPPLEMENTARY INFORMATION:

I. Background

On November 8, 2019, the Centers for Medicare & Medicaid Services published a final rule titled, “Medicare Program; End- Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Amendments, Standard Elements

for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements” (84 FR 60648). The rule became effective January 1, 2020, harmonizing the lists of DMEPOS items created by former rules and establishing one “Master List of DMEPOS Items Potentially Subject to Face-to-Face Encounter and Written Orders Prior to Delivery and/or Prior Authorization Requirements” (the “Master List”). The rule provided that items would be selected from the Master List for inclusion on the Face-to-Face Encounter and Written Orders Prior to Delivery List and/or Prior Authorization List through the **Federal Register**. It also clarified that certain items (that is, power mobility devices (PMDs)) require a face-to-face encounter per statute and would remain on the list indefinitely.

On January 13, 2022, in accordance with the November 2019 final rule (84 FR 60648), we selected codes from the Master List and published the first iteration of the Required Face-to-Face Encounter and Written Order Prior to Delivery List (hereinafter referred to as “F2F/WOPD List”). (For more detailed information see 87 FR 2051). The F2F/WOPD List became effective on April 13, 2022. It included 46 K-codes representative of PMDs as well as 7 Healthcare Common Procedure Coding System (HCPCS) that describe other items.

II. Provisions of the Document

This document announces that CMS has selected an additional set of items to be added to the F2F/WOPD List.

A. Reiteration of the Face-to-Face Encounter and Written Order Prior to Delivery List Process and DMEPOS Items Currently on The List

The F2F/WOPD List, as described at §410.38(c)(8), is comprised of PMDs, per statute, and those items selected from the Master List (which is described in §§ 410.38(c)(7) and 414.234(b)). Items on this list require a face-to-face encounter and a written order prior to delivery as a condition of payment.

In the November 2019 final rule, we stated that since the face-to-face encounter and written orders are statutorily required for PMDs, per section 1834(a)(1)(E)(iv) of the Act, they are included on the Master List and the F2F/WOPD List in accordance with our statutory obligation, and will remain

there. These codes, as listed in Table 1, will remain on the F2F/WOPD List.

**TABLE 1: STATUTORILY REQUIRED POWER MOBILITY DEVICES
(CURRENTLY ON THE LIST)**

| HCPCS | Description |
|--------------|--|
| K0800 | Power Operated Vehicle, Group 1 Standard, Patient Weight Capacity Up To And Including 300 Pounds |
| K0801 | Power Operated Vehicle, Group 1 Heavy Duty, Patient Weight Capacity, 301 To 450 Pounds |
| K0802 | Power Operated Vehicle, Group 1 Very Heavy Duty, Patient Weight Capacity 451 To 600 Pounds |
| K0806 | Power Operated Vehicle, Group 2 Standard, Patient Weight Capacity Up To And Including 300 Pounds |
| K0807 | Power Operated Vehicle, Group 2 Heavy Duty, Patient Weight Capacity 301 To 450 Pounds |
| K0808 | Power Operated Vehicle, Group 2 Very Heavy Duty, Patient Weight Capacity 451 To 600 Pounds |
| K0813 | Power Wheelchair, Group 1 Standard, Portable, Sling/Solid Seat And Back, Patient Weight Capacity Up To And Including 300 Pounds |
| K0814 | Power Wheelchair, Group 1 Standard, Portable, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds |
| K0815 | Power Wheelchair, Group 1 Standard, Sling/Solid Seat And Back, Patient Weight Capacity Up To And Including 300 Pounds |
| K0816 | Power Wheelchair, Group 1 Standard, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds |
| K0820 | Power Wheelchair, Group 2 Standard, Portable, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds |
| K0821 | Power Wheelchair, Group 2 Standard, Portable, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds |
| K0822 | Power Wheelchair, Group 2 Standard, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds |
| K0823 | Power Wheelchair, Group 2 Standard, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds |
| K0824 | Power Wheelchair, Group 2 Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds |
| K0825 | Power Wheelchair, Group 2 Heavy Duty, Captains Chair, Patient Weight Capacity 301 To 450 Pounds |
| K0826 | Power Wheelchair, Group 2 Very Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds |
| K0827 | Power Wheelchair, Group 2 Very Heavy Duty, Captains Chair, Patient Weight Capacity 451 To 600 Pounds |
| K0828 | Power Wheelchair, Group 2 Extra Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More |
| K0829 | Power Wheelchair, Group 2 Extra Heavy Duty, Captains Chair, Patient Weight Capacity 601 Pounds Or More |
| K0835 | Power Wheelchair, Group 2 Standard, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds |
| K0836 | Power Wheelchair, Group 2 Standard, Single Power Option, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds |
| K0837 | Power Wheelchair, Group 2 Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds |
| K0838 | Power Wheelchair, Group 2 Heavy Duty, Single Power Option, Captains Chair, Patient Weight Capacity 301 To 450 Pounds |
| K0839 | Power Wheelchair, Group 2 Very Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds |
| K0840 | Power Wheelchair, Group 2 Extra Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More |
| K0841 | Power Wheelchair, Group 2 Standard, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds |
| K0842 | Power Wheelchair, Group 2 Standard, Multiple Power Option, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds |
| K0843 | Power Wheelchair, Group 2 Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds |
| K0848 | Power Wheelchair, Group 3 Standard, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds |
| K0849 | Power Wheelchair, Group 3 Standard, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds |
| K0850 | Power Wheelchair, Group 3 Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds |
| K0851 | Power Wheelchair, Group 3 Heavy Duty, Captains Chair, Patient Weight Capacity 301 To 450 Pounds |
| K0852 | Power Wheelchair, Group 3 Very Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds |
| K0853 | Power Wheelchair, Group 3 Very Heavy Duty, Captains Chair, Patient Weight Capacity, 451 To 600 Pounds |
| K0854 | Power Wheelchair, Group 3 Extra Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More |
| K0855 | Power Wheelchair, Group 3 Extra Heavy Duty, Captains Chair, Patient Weight Capacity 601 Pounds Or More |
| K0856 | Power Wheelchair, Group 3 Standard, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds |
| K0857 | Power Wheelchair, Group 3 Standard, Single Power Option, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds |
| K0858 | Power Wheelchair, Group 3 Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds |
| K0859 | Power Wheelchair, Group 3 Heavy Duty, Single Power Option, Captains Chair, Patient Weight Capacity 301 To 450 Pounds |
| K0860 | Power Wheelchair, Group 3 Very Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds |
| K0861 | Power Wheelchair, Group 3 Standard, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds |
| K0862 | Power Wheelchair, Group 3 Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds |
| K0863 | Power Wheelchair, Group 3 Very Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds |
| K0864 | Power Wheelchair, Group 3 Extra Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More |

Section 1834(a)(11)(B) of the Act authorizes the Secretary to select other DMEPOS HCPCS codes that will require a face-to-face encounter and written order prior to delivery as a condition of payment. The November 2019 final rule established a process of placing other DMEPOS items, in addition to PMDs, on the F2F/WOPD List. We included in the 2022 **Federal Register** seven additional DMEPOS HCPCS codes not required by statute. These items were selected from the Master List to be placed on the F2F/WOPD List and are listed in Table 2. The items listed in both Table 1 and Table 2

will remain on the F2F/WOPD list.

**TABLE 2: NON-STATUTORILY REQUIRED DMEPOS ITEMS
(CURRENTLY ON THE LIST)**

| HCPCS | Description |
|-------|--|
| E0748 | Osteogenesis Stimulator, Electrical, Non-Invasive, Spinal Applications |
| L0648 | Lumbar-Sacral Orthosis, Sagittal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Off-The-Shelf |
| L0650 | Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panel(S), Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Off-The-Shelf |
| L1832 | Knee Orthosis, Adjustable Knee Joints (Unicentric Or Polycentric), Positional Orthosis, Rigid Support, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise |
| L1833 | Knee Orthosis, Adjustable Knee Joints (Unicentric Or Polycentric), Positional Orthosis, Rigid Support, Prefabricated, Off-The Shelf |
| L1851 | Knee Orthosis (KO), Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated, Off-The-Shelf |
| L3960 | Shoulder Elbow Wrist Hand Orthosis, Abduction Positioning, Airplane Design, Prefabricated, Includes Fitting And Adjustment |

B. New DMEPOS Items Being Placed on the Face-to-Face Encounter and Written Order Prior to Delivery List

PMDs are included on the F2F/WOPD List per statutory obligation. For the other DMEPOS items, we consider factors such as operational limitations, item utilization, cost-benefit analysis (for example, comparing the cost of review versus the anticipated amount of improper payment identified), emerging trends (for example, billing patterns, medical review findings), vulnerabilities identified in official agency reports, or other analysis such as acute needs and pandemic impacts.

When selecting items, we balance our program integrity goals with the needs of Medicare enrollees, particularly those in need of medical devices to assist with functional activities and ambulation within their home. In consideration of access issues, we note that the face-to-face regulation at 42 CFR 410.38(d)(2)(ii) allows for use of telehealth, provided that the requirements in 42 CFR 410.78 and 414.65 are met.

The first iteration of the F2F/WOPD list was released earlier in the COVID-19 Public Health Emergency (PHE). The unprecedented PHE, coupled with the list's newness, led the Agency to initially proceed with the selection of seven items. Feedback received to date has been positive. We have not been notified of any issues related to Medicare beneficiaries' access, and billing trends have been consistent with anticipated volumes.

Lower limb orthoses (LLO) and lumbar-sacral orthoses (LSO) have been identified by CMS' Comprehensive Error Rate Testing (CERT) program as two of the top 20 DMEPOS service types with improper payments over the past several years, and have been associated with recent fraud schemes. In 2021, LLOs had an improper payment rate of 50.6 percent and LSOs had an improper payment rate of 44.2 percent. The CERT improper payment rate is a measurement of payments that do not meet Medicare requirements. Insufficient documentation and medical necessity are the top two LLO and LSO errors noted in the 2021 CERT report.¹

In an effort to ensure practitioner involvement, via in-person face-to-face encounters or telehealth encounters meeting Medicare's regulatory requirements, we are adding the following 10 additional HCPCS codes for inclusion on the Required F2F/WOPD List. We are releasing these codes in this **Federal Register** publication with 90 days' notice prior to implementation. At this time, we are not removing any items from the F2F/WOPD List.

TABLE 3: NEW NON-STATUTORILY REQUIRED DMEPOS ITEMS

| HCPCS | Description |
|--------------|--|
| L0631 | Lumbar-Sacral Orthosis, Sagittal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise |
| L0637 | Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise |
| L1843 | Knee Orthosis, Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise |
| L1932 | Ankle Foot Orthosis, Rigid Anterior Tibial Section, Total Carbon Fiber Or Equal Material, Prefabricated, Includes Fitting And Adjustment |
| L1940 | Ankle Foot Orthosis, Plastic Or Other Material, Custom-Fabricated |
| L1951 | Ankle Foot Orthosis, Spiral, (Institute Of Rehabilitative Medicine Type), Plastic Or Other Material, Prefabricated, Includes Fitting And Adjustment |
| L1960 | Ankle Foot Orthosis, Posterior Solid Ankle, Plastic, Custom-Fabricated |
| L1970 | Ankle Foot Orthosis, Plastic With Ankle Joint, Custom-Fabricated |
| L2005 | Knee Ankle Foot Orthosis, Any Material, Single Or Double Upright, Stance Control, Automatic Lock And Swing Phase Release, Any Type Activation, Includes Ankle Joint, Any Type, Custom Fabricated |
| L2036 | Knee Ankle Foot Orthosis, Full Plastic, Double Upright, With Or Without Free Motion Knee, With Or Without Free Motion Ankle, Custom Fabricated |

The current complete F2F/WOPD List is available on the following CMS website:

¹2021 Medicare Fee-for-Service Supplemental Improper Payment Data <https://www.cms.gov/files/document/2021-medicare-fee-service-supplemental-improper-payment-data.pdf>

<https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/FacetoFaceEncounterRequirementforCertainDurableMedicalEquipment>.

We believe transparency and education will aid in compliance with these payment requirements and continued access. As such, we will make information widely available to the public at appropriate literacy levels regarding face-to-face encounter requirements, written order prior to delivery requirements, and necessary documentation for items on F2F/WOPD List.

We continue to believe greater practitioner involvement in the care of Medicare enrollees in need of items included on the F2F/WOPD List will help further our program integrity goals of reducing fraud, waste, and abuse. It will also help ensure Medicare enrollee receipt of items specific to their medical needs. For items on the F2F/WOPD List, the written order/prescription must be communicated to the supplier prior to delivery. For such items, we require the treating practitioner to have a face-to-face encounter with the Medicare enrollee within the 6 months preceding the date of the written order/prescription. If the face-to-face encounter is a telehealth encounter, the requirements of 42 CFR 410.78 and 414.65 must be met for DMEPOS coverage purposes.

Consistent with §410.38(d), the face-to-face encounter must be documented in the pertinent portion of the medical record (for example, history, physical examination, diagnostic tests, summary of findings, progress notes, treatment plans or other sources of information that may be appropriate). The supporting documentation must include subjective and objective beneficiary specific information used for diagnosing, treating, or managing a clinical condition for which the DMEPOS item(s) is ordered. Upon request by CMS or its review contractors, a supplier must submit additional documentation to support and substantiate the medical necessity for the DMEPOS item.

Section 410.38(c)(8) of the Act states new additions to the F2F/WOPD list will be communicated to the public and effective no less than 60 days after a **Federal Register** document publication and a CMS website posting. To assist stakeholders in preparing for implementation of the new items, these changes will become effective 90 days after publication of this rule. Stakeholders may

refer to the CMS website posting for more information on the implementation date.

III. Collection of Information Requirements

This document announces the selection of additional HCPCS codes to be placed on the F2F/WOPD List. These updates to the F2F/WOPD List do not constitute information collections requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

IV. Regulatory Impact Statement

We have examined the impact of this regulatory document as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A Regulatory Impact Analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with economically significant effects (\$100 million or more in any 1 year). This regulatory document is not significant and does not reach the economic threshold and thus is not considered a major regulatory document.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$8.0 million to \$41.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an

analysis for the RFA because we have determined, and the Secretary certifies, that this regulatory document will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this regulatory document will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately \$165 million. This regulatory document will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule or other regulatory document) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulatory document does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this document was reviewed by the Office of Management and Budget.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the

Federal Register.

Dated: January 11, 2023.

Lynette Wilson,

Federal Register Liaison,

Centers for Medicare & Medicaid Services.

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